

NATIONAL INSTITUTES OF HEALTH (NIH)  
RECOMBINANT DNA ADVISORY COMMITTEE (RAC)  
130<sup>th</sup> MEETING  
ROCKVILLE HILTON & EXECUTIVE MEETING CENTER  
SEPTEMBER 12, 2012

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*Wednesday, September 12, 2012*

2:00 PM                    **Call to Order and Opening Remarks**

Yuman Fong, M.D., RAC Chair

Tab 2711                    For Your Information  
Notice of Meeting  
Conflict of Interest Guidance

2:05 PM                    **Minutes of RAC Meeting June 19, 2012**

RAC Reviewers:        Saswati Chatterjee, Ph.D.  
Rebecca Dresser, J.D.

2:10 PM                    **Discussion of Human Gene Transfer Protocol #1206-1169:** *Phase I/II Study of Adoptive Immunotherapy after Allogeneic HCT with Virus Specific CD8+ T Cells that have been Transduced to Express a WT1-specific T Cell Receptor for Patients with High Risk or Relapsed AML, MDS, or CML*

**PIs:**                        Merav Bar, M.D., University of Washington/ Fred  
Hutchinson Cancer Research Center, Seattle, WA  
and  
Aude Chapuis, M.D., University of Washington/  
Fred Hutchinson Cancer Research Center

RAC Reviewers:        Marie-Louise Hammarskjöld, M.D., Ph.D.  
Donald Kohn, M.D.  
Marshall Strome, M.D., M.S.

Tab 2712                    Protocol

Tab 2713                    OBA Summary  
OBA Letters to PI on In-Depth RAC Review and  
Public Discussion  
Reviews from Drs. Kohn, Hammarskjöld, and  
Strome  
PI's Response

*(continued) Wednesday, September 12, 2012*

3:20 PM                    **Public Comment**

3:30 PM                    **BREAK**

3:45 PM                    **Gene Transfer Safety Assessment Board Report**

RAC Reviewers:        Andrew Badley, M.D.  
                              E. Antonio Chiocca, M.D., Ph.D.  
                              Yuman Fong, M.D.  
                              Hans-Peter Kiem, Ph.D., M.D.  
                              Donald Kohn, M.D.  
                              Marshall Strome, M.D., M.S.

Tab 2714                Responses to M-I-C-1  
                              Protocol List  
                              Protocols Not Selected for In-Depth Review and  
                              Public Discussion

4:00 PM                    **Updates to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acids Molecules***

Presenters:             Jacqueline Corrigan-Curay, M.D., J.D.  
                              Office of Biotechnology Activities, National  
                              Institutes of Health, Bethesda, MD  
                              and  
                              Joseph Kanabrocki, Ph.D., University of Chicago,  
                              Chicago, IL

Tab 2715                Background Material

4:40 PM                    **Public Comment**

4:45 PM                    **Adjournment**